than vaginal births.

Ratio of Deaths per 100,000

Spontaneous Vaginal Birth:	..6 deaths	1 per 16,666 deliveries
Auto Accidents:	20 deaths	1 per 5,000 women 14-34
Most Dangerous Occupation:	22 deaths	cab drivers NYC
Breast Cancer:	26 deaths	1 per 3,846 women Dx
Cesarean Section:	31 deaths	1 per 3,225 surgeries

Cesarean surgeries are directly associated with increased rates of maternal mortality. This means that out of 4.5 million births last year, approximately 1395 new mothers died last year from the complications of cesarean surgery, compared to 270 for vaginal birth -- an "excess maternal mortality of 1125 women. Cesarean birth is more dangerous than the most dangerous occupation in the US -- driving a cab. Preventing unnecessary cesarean surgeries prevents maternal mortality. Midwifery management prevents cesarean surgeries. Prevention of medically-unnecessary reproductive surgeries also increases opportunities for valuable maternal-child interaction during the postpartum, promotes family bonding and wellbeing, increases the rate of successful breastfeeding and reduces the cost of maternity care.

This is not an abstract conversation. We had a maternal death recently in our local hospital after a medical unnecessary cesarean following a medically unnecessary induction because the doctor feared the baby might be getting "too big" To prevent a theoretical future complications, he first induced her and when labor didn't progress, he sectioned her. She died two days later of infection.

Obstetrics for Healthy Mothers is Experimental Medicine

Obstetrics for normal birth has always been experimental medicine in that common interventions and treatment modalities were never

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The Sherman Act - Antitrust Legislation

Ryan Blanch

Provided by *The Blanch Law Firm*

THE BLANCH LAW FIRM

The Sherman Anti-Trust Act is the fundamental basis of American antitrust legislation. While later laws would expand upon the definition and enforcement of antitrust as a legal concept, the Sherman Act has been the foundation of antitrust law for over one hundred years in the United States.

Introduction

The Sherman Anti-Trust Act is the fundamental basis of American antitrust legislation. While later laws would expand upon the definition and enforcement of antitrust as a legal concept, the Sherman Act has been the foundation of antitrust law for over one hundred years in the United States.

Over that period of time, the definition of and goals of antitrust enforcement by the government has been shaped by statute, Presidents, and the Courts. It was during then-President Clinton's administration that the Department of Justice prosecuted Microsoft in U.S. v. Microsoft, as well as formally denying the MCI Sprint telecommunications merger.

The Sherman Act itself consists of seven sections - of those seven, only the first two are considered relevant for present-day antitrust.

Section 1. Trusts, etc., in restraint of trade illegal; penalty

Every contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is declared to be illegal. Every person who shall make any contract or engage in any combination or conspiracy hereby declared to be illegal shall be deemed guilty of a felony, and, on conviction thereof, shall be punished by fine not exceeding $10,000,000 if a corporation, or, if any other person, $350,000, or by imprisonment not exceeding three years, or by both said punishments, in the discretion of the court.

Section 2. Monopolizing trade a felony; penalty

Every person who shall monopolize, or attempt to monopolize, or combine or conspire with any other person or persons, to monopolize any part of the trade or commerce among the several States, or with foreign nations, shall be deemed guilty of a felony, and, on conviction thereof, shall be punished by fine not exceeding $10,000,000 if a corporation, or, if any other person, $350,000, or by imprisonment not exceeding three years, or by both said punishments, in the discretion of the court.

Plainly, the Sherman Act criminalizes not only the act of restraint of trade and monopoly, but any attempt, intent, or conspiracy to engage in restraint of trade or monopoly.

One major criticism of the Sherman Act is an unexplained failure to explain key terminology of the act. The Sherman Act does not explicitly define either restraint of trade or monopoly. With these key terms undefined, wide authority is granted de facto to the Government and Courts. Thus, with the goal of clarification in mind, in 1914 the Clayton Antitrust Act was passed.

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restraint of trade

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March 9. 2009

In Re: HB 390, rebuttal to Dr. Gillis' comments

Dear Senator Kaufmann

My name is Brian Maffly. I am the surviving husband of Karen Sclafani. Karen died of an obstetrical hemorrhage at Bozeman Deaconess Hospital in February 2004. I believe that mistakes were made in the management of her labor and delivery and, after retaining counsel, I brought suit in the District Court in Gallatin County arising out of Karen's death. During the pendency of that case, it became my understanding from information we obtained there had been only one maternal death at BDH from the period of 2004 through the completion of my case about one year ago. That death was my wife Karen. My case is now settled and the terms of that settlement are confidential by agreement of all concerned.

Before Karen was admitted to BDH, she chose Mikelann Caywood Baerg to provide prenatal and labor and delivery services for our hoped for homebirth. As it turned out, however, Karen developed a complication of pregnancy called pre-eclampsia, which was suspected by Mikelann late during Karen's pregnancy. For that reason, Mikelann felt that the development of this condition was beyond the scope of her practice and she recommended referral to a physician specializing in obstetrics. We accepted this advice and that is what led to Karen's admission to Bozeman Deaconess Hospital on Feb. 4, 2004. From that point forward, Karen's labor and delivery were managed by trained obstetricians and the Bozeman Deaconess staff. Mikelann was no longer involved. In the legal case we brought, we did not allege, nor did we believe, that Mikelann exceeded her scope of practice or committed any medical mistake in her provision of care to Karen. To my knowledge, no other party who was a defendant in our case made any formal allegation critical against Mikelann either. The responsibility for Karen's death was vigorously denied by all concerned.

Mikelann has forwarded to me a letter directed to you by Shaun Gillis, who is apparently an obstetrical physician in Bozeman. In this letter, Dr. Gillis, who played no role in our litigation or in Karen's care, asserts that

"the midwife who owns the birth center in Bozeman" does not know her limits, which ultimately played a role in the unnecessary death of a patient in 2005." Since it is my understanding that this could only refer to my wife Karen, I felt a responsibility to send you this letter. If Dr. Gillis is referring to my wife Karen Sclafani as the "unnecessary death of a patient in 2005," then I feel it my duty to inform you that we did not accuse Mikelann of causing Karen's death, do not now believe that she made a medical mistake causing Karen's death, and that no one else in my case ever formally alleged anything to that affect. I have no expertise on the other issues addressed in Dr. Gillis' letter and will not comment on them. I hope you find this helpful in assessing the sincerity and credibility of this midwife in who we reposed much confidence, and whose conduct lead to the her own termination of her care as a midwife judging it to be "beyond the scope of a midwife"-- the opposite of what she is being accused of in this letter.

Sincerely, Brian Maffly

Cc: Mikelann Caywood Baerg

The Standards for Birth Centers were approved by the Board of Directors of the American Association of Birth Centers on March 30, 1985.

Revisions recommended by the Standards Committee were approved by the Board of Directors and the membership on:

April 4, 1987

September 18, 1992

October 1, 1995

September 27, 1998

September 24, 2000

September 21, 2003

October 7, 2007

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INTRODUCTION

National Standards were established to provide a tool for measuring the quality of services provided to childbearing families in birth centers. Quality is a relative term defined by predetermined characteristics, traits, properties or attributes. Therefore, quality improvement is a continuing process toward achieving the predetermined characteristics, traits, properties or attributes defined by the standards for birth centers.

Quality improvement is an ongoing function that is both external and internal to birth center operation. Licensure and accreditation constitute two arms of external evaluation of quality. Licensing agencies protect the public by monitoring compliance to codes, ordinances and a variety of regulations. This first level of external quality control requires that the birth center meet defined criteria for state licensure in order to operate as a business or health care facility. The level of quality required for licensure, however, may vary from one locality to another. Some states and municipalities are non-specific or uneven in their requirements for regulations, while other states may be very specific and uniform in the level of requirements for safe operation.

A second level of external quality evaluation is accreditation. The standards and attributes for accreditation are uniformly applied in all localities, thereby eliminating state and local inconsistency. It is a voluntary program that places the level of quality desired above that which an individual state requires.

The internal quality improvement program is an ongoing evaluation by birth center staff and childbearing families. It begins at the earliest stages of planning for a birth center and consists of a systems approach to evaluation of operation and services. With careful planning, new birth centers have the opportunity to build evaluation mechanisms into all facets of the organization and operation from the first day of operation. If attention is given to establishing a strong program of quality management during the planning of the birth center, application for licensure and accreditation are simply a form of external review – an opportunity to be evaluated or measured by established yardsticks for required and desired levels of excellence.

AABC STANDARDS DEVELOPMENT

The first standards of the American Association of Birth Centers (formerly the National Association of Childbearing Centers) represent an effort that evolved over more than a decade beginning with the design of the demonstration Childbearing Center in 1975 by Maternity Center Association (now known as Childbirth Connection) of New York. That demonstration included:

1. Identification of criteria for low risk pregnancy and birth (sample available through AABC).

2. Development of policies and procedures for operation of a birth center within the existing system of health care (sample available through AABC).

3. Design of record forms including an extensive informed consent (sample available through AABC).

4. A health record that reflects the physical care provided, as well as, the instruction of clients on health relating to pregnancy, birth, and early parenting.

5. Evaluation mechanism for all aspects of the program offered.

The Maternity Center Association also took the concept of the birth center through the official government agencies responsible for protecting the public's health and welfare and met all of the characteristics of quality assurance required by a certificate of need, the health code, building codes, fire and safety code, the federal requirements for controlled substance use and, in the absence of birth center-specific regulations, the regulations for a license to operate as a Diagnostic and Treatment Center in New York State.

In 1979 Maternity Center Association sponsored a national tour of fourteen operating birth centers in fourteen states. The tour was followed by a study of eleven of those centers by Anita Barbey, DrPH that was reported in the Lancet in 1982. The study brought attention to an urgent need for birth centers to be able to communicate on matters of common interest and concern.

In 1981 the Cooperative Birth Center Network was established as a program of Maternity Center Association under a grant from the John A. Hartford Foundation to promote quality assurance in the growth of birth centers and to communicate the development of the birth center concept at policy, provider and public levels. In view of the projections

for growth and the lack of mechanism to assure quality of services, high priority was given to the development of the Recommendations and Rationale for Regulation of Birth Centers (CBCN News, Vol. 1, Nos. 2-3), support for the development of the American Public Health Association's Guidelines for Licensing and Regulating Birth Centers (CBCN News, Vol. 1, No. 4) and finally, development of national standards and a mechanism for accreditation.

The Childbearing Center of the Maternity Center Association was the first center to seek accreditation. It had been accredited since 1979 by the National League for Nursing/American Public Health Association (NLN/APHA) Council on Accreditation of Community Health Agencies. In 1982 and 1983 meetings were held with the staff of the NLN/APHA accrediting services to examine the feasibility of birth center accreditation through the established mechanisms of NLN/APHA. Attempts were made to adapt the NLN/APHA standards to fit the special needs of birth centers. However, as the numbers of birth centers increased, it became apparent that obstetricians, family practice physicians and hospitals, as well as nurse-midwives and community health agencies, constituted an expanding market in the establishment of birth centers. Birth center-specific standards and criteria needed to be broadly developed to administer an accreditation program effectively and efficiently for all birth centers.

The possibility of accreditation by the Accreditation Association for Ambulatory Health Care, Inc. (AAAHC) and the Joint Commission on Accreditation of Health Organizations (JCAHO) was also explored. The structure of these organizations, the cost of their services and the fact they would only evaluate hospital or physician-owned centers did not seem to be a viable option for birth centers at that time.

It was decided that a multidisciplinary approach to standards was needed. Thus, the President of the Board of AABC, accompanied by representatives of concerned governmental agencies, consulted with the American College of Obstetricians and Gynecologists (ACOG). ACOG responded that they could not be involved in accreditation for legal reasons and would not be able to participate in writing standards.

The belief that birth centers should be involved in establishing national standards of excellence for their own operation and services motivated MCA to seek funds to work with AABC to establish standards specifically for birth centers and pilot test a cost effective mechanism for accreditation.

Partial funding for the project was obtained by Maternity Center Association from the Pew Charitable Trust. The Pew Grant funded the initial phase to develop the standards and pilot test the application of these standards in the evaluation of ten birth centers

selected to reflect the variety of types of centers in terms of ownership, staffing, location and populations served.

The process of accreditation developed by AABC under the pilot program provided the foundation for establishing the independent Commission for the Accreditation of Birth Centers.

The Standards Committee of the AABC is responsible for periodically reviewing the Standards to assuren that they remain consistent with evolving evidence-based maternity care. The Standards Committee, a standing committee of the AABC, has equal representation from the AABC and the Commission for the Accreditation of Birth Centers (CABC), with a Chair who is an AABC BOD member.

The Standards are owned by the AABC, and require membership approval for revision. The CABC BOD then develops specific indicators for assessment of compliance with the Standards.

The American Association of Birth Centers recognizes the many people, too numerous to identify, who participated in this effort. We are grateful for their commitment to developing quality services in birth centers.

I. PLANNING

STANDARD

The birth center assesses the needs of the childbearing community in developing services and programs.

Attributes Required for Compliance with Standard:

1. The general geographical area served is defined.
2. Demographic data and vital statistics of the community served are assessed periodically.
   A. Availability of and access to maternal and newborn services including practitioners, hospital obstetrical and newborn services, home birth services, family-centered maternity care programs, birth rooms/suites, clinics for disadvantaged families, laboratory services, supplementary social and welfare services, childbirth education and parent support programs are evaluated.
   B. The birth center periodically assesses its impact on the community and assesses the needs of childbearing families in the population served for purpose of program planning and development.
   C. Changes in the population, the environment, regulations, legislation, reimbursement, access to and availability of maternal and newborn services in the community are analyzed for impact on the operation of the childbearing center.

II. ORGANIZATION

STANDARD

The birth center is, or is part of, a legally constituted organization with a governing body that establishes policy, lines of responsibility and accountability and, either directly or by delegated authority to qualified individuals, is responsible for fiscal management and operation of the center.

Attributes Required for Compliance with Standard:

1. The birth center is governed as an organization that is separate from other health, hospital or medical services and has its own governing body, or is part of a larger legally constituted healthcare organization and has representation to that governing body.

2. Governing body or the designated birth center directors meet regularly to execute responsibilities for operation of the center and maintains minutes of the meeting.

3. Names and addresses of all owners or controlling parties, directors and officers are maintained and there is a policy on conflict of interest disclosure.

4. Governing body responsibilities, direct or delegated, include but are not limited to:
   A. Formulation of missions, goals and a long range plan for the center
   B. Development of organizational structure and bylaws, which clearly delineate lines of authority and responsibility
   C. Appointment of qualified administrative director
   D. Appointment of qualified director of the professional staff
   E. Approval of policies and procedures for the operation of the center
   F. Approval of qualifications of applicants for professional staff
   G. Approval of a program of quality improvement for the operation of the center and the care provided
   H. Review and action on all legal matters relating to the operation of the center
   I. Financial management and accountability

J. Establishing charges for services

K. Prohibition of discrimination in operation and provision of services

L. Approval of all contracts and agreements with individuals or service agencies, such as hospitals, laboratories, emergency transport, consulting specialists, teaching institutions, and organizations conducting research

M. Access to and retrieval of all revenue and expense information specific to the birth center

5. The governing body establishes a mechanism for consumer advice on the services and functioning of the birth center.

III. ADMINISTRATION

STANDARD

The birth center is administered according to the mission, goals and policies of the governing body in a manner that assures financial viability while promoting high quality services responsive to the needs of the population served.

Attributes Required for Compliance with Standard:

1. The mission, philosophy and goals of the birth center are clearly stated.
2. A qualified individual is designated by the governing body as administrative director with authority, responsibility and accountability for overall center administration. There is a plan for the operation of the center in the absence of the administrative director.
3. There is evidence of adherence to generally accepted accounting principles including but not limited to a review of financial statements every six (6) months and approval of the annual budget by documentation in minutes from meetings of the governing board or its directors.
4. There is a management plan for investments and capital expenditures.
5. There are policies and procedures for maintenance of equipment, building and grounds, as well as control of the use of the facility.
6. There is orderly maintenance and secure storage of official documents of the center.
7. Personnel policies and procedures are maintained (See section on Personnel).
8. Contracts for student education or field experience are approved by the governing body or its designee.
9. The center carries liability insurance. Where liability insurance is not available, the center notifies clients that the center does not carry liability insurance.

10. There are agreements and/or policies and procedures for interaction with other agencies, institutions and individuals for services to clients including but not limited to:
    A. Obstetric/newborn acute care in licensed hospitals
    B. Transport services
    C. Obstetric consultation services
    D. Pediatric consultation services
    E. Laboratory and diagnostic services
    F. Childbirth education/parent education support services
    G. Home health care services.
11. All contracts, agreements, policies and procedures are reviewed annually and updated as needed.
12. There is a plan for informing the community of the services of the center.
13. Complies with applicable local, state and federal regulations for protection of client privacy and safety.

IV. FACILITY, EQUIPMENT & SUPPLIES

STANDARD

The birth center establishes and maintains a safe, home-like environment for healthy women anticipating an uncomplicated labor and birth with space for furnishings, equipment and supplies commensurate to comfortable accommodation for the number of childbearing families served and the personnel providing services.

Attributes Required for Compliance with Standard:

FACILITY

1. Complies with regulations for licensure of birth centers if established for its jurisdiction.
2. Complies with applicable local, state and federal codes, regulations and ordinances for construction, fire prevention, public safety and access.
3. In the absence of community fire regulations the birth center maintains functioning smoke alarms, appropriately placed fire extinguishers to control limited fires and emergency fire lighting; identifies exits; protects stairwells with fire doors.
4. Maintains a record of routine periodic inspections by Health Department, Fire Department, Building inspectors and other officials concerned with public safety, as required by the center's local jurisdiction.
5. Provides instruction of all personnel on fire safety and conducts at least semiannual evacuation drills.
6. Prohibits smoking in the birth center.
7. Guards against environmental factors that may cause injury from falls, electrical shock, poisoning and burns; with particular attention to hazards to children such as uncovered electrical outlets, unsafe toys, unprotected stairs and unlocked storage cabinets as well as walkways, parking lots and outside play areas.
8. Provides adequate ventilation and lighting.

9. Provides adequate space for caseload and personnel and insures privacy for women and childbearing families including but not limited to:
   A. Business operations
   B. Secure medical records storage
   C. Waiting reception area
   D. Exam rooms
   E. Family room and play area for children
   F. Bath and toilet facilities for families, laboring women and staff
   G. Birth rooms
   H. Staff area
   I. Educational facilities/library
   J. Utility and work area
   K. Storage
   L. Area for emergency care
   M. Accommodation for a non-ambulatory family member (non-ambulatory childbearing women are not usually cared for in birth centers).
10. Provides adequate housekeeping services to maintain a sanitary, home-like environment.
11. Provides adequate hand-washing facilities for childbearing families and personnel.
12. Provides adequate space for coats, boots and umbrellas in inclement weather where appropriate.
13. Provides adequate sanitary trash storage and removal including biomedical waste and human tissue.
14. Has a disaster plan in place, including equipment or plan for snow removal where appropriate, and to secure the facility in the event of floods, major storms, etc.

EQUIPMENT

15. A readily accessible emergency cart or tray for the mother is equipped to carry out the written emergency procedures of the center and securely placed with a written log of routine maintenance for readiness.

16. A readily accessible emergency cart or tray for the newborn is equipped to carry out the written emergency procedures of the center and securely placed with a written log of routine maintenance for readiness.

17. Properly maintained equipment for routine care of women and neonates including but not limited to:
    A. A heat source for infant examination or resuscitation
    B. Transfer isolette or demonstrated capability of ready access to transport
    C. Sterilizer or demonstration of sterilizing capability
    D. Blood pressure equipment, thermometers, fetoscope/doptone, equipment for newborn exam.
    E. Intravenous equipment
    F. Oxygen equipment for mother and newborn
    G. Instruments for delivery, episiotomy and repair.

18. Provides properly maintained accessory equipment which includes but is not limited to:
    A. Conveniently placed telephones
    B. Portable lighting
    C. Kitchen equipment usually found in home for light refreshment
    D. Laundry equipment usually found in home or contracted laundry services.

SUPPLIES

19. The inventory of supplies is sufficient to care for the number of childbearing women and families registered for care.

20. Shelf life of all medications, I.V. fluids and sterile supplies is monitored.

21. Supplies such as needles, syringes, and prescription pads are appropriately stored to avoid public access.

22. Controlled drugs are maintained in double-locked, secured cabinets with a written procedure for accountability.

23. Used hazardous supplies, such as needles and expired drugs, are disposed of properly.

V. QUALITY OF SERVICES

STANDARD

The birth center provides high quality, family-centered, maternal and newborn services to healthy women anticipating an uncomplicated pregnancy, labor and birth that reflect the following:

- Applicable professional standards for conduct of the practitioners responsible for services rendered;
- Available scientific evidence;
- Recognition of the basic human rights of the childbearing woman and her family.

Attributes Required for Compliance with Standard

1. That the rights and responsibilities of the woman and her family, however she defines her family, are clearly delineated in the center's policies and procedures and communicated to the childbearing family on acceptance for care and that the client's rights include but not be limited to:
   A. Be treated with respect, dignity and consideration
   B. Be assured of confidentiality
   C. Be informed of the benefits, risks and eligibility requirements of an out-of-hospital labor and birth
   D. Be informed of those services provided by the center and services provided by contract, consultation and referral
   E. Be informed of the identity and qualifications of care providers, consultants and related services and institutions
   F. Be informed of all diagnostic procedures and reports, all recommendations and treatments
   G. Participate in decisions relating to the plan for management of her care and all changes in that plan once established including referral or transfer to other practitioners or other levels of care.
   H. Be provided with a written statement of fees for services and responsibilities for payment

I. Be informed of the center's plan for provision of emergency and non-emergency care in the event of complications to mother and newborn

J. Be informed of the client's rights with regards to participation in research or student education programs

K. Be informed of the center's plan for hearing grievance

L. Be informed of the liability insurance status of practitioners on request.

2. That the center provide or demonstrate availability of a range of services to meet physical, emotional, socio-economic, informational and medical needs of the individual client while under care including but not limited to:

A. An orientation to the facility fees and services of the center

B. Written information, including a glossary of terms, on the established criteria for admission to, and continuation in, the birth center program of care as appropriate for the demographics of the center's client population.

C. Prenatal care (may be provided at related practitioner or clinic site)

D. A program of education for pregnancy, labor, breastfeeding, infant care, early discharge, parenting, self-care/self-help, sibling preparation

E. Laboratory services

F. 24-hour telephone consultation

G. Library resources

H. Intrapartum care

I. Light nourishment during labor and postpartum

J. Immediate postpartum care

K. Home or office follow-up for mother and newborn

L. There shall be strong evidence that the birth center is addressing domestic violence as an issue with birth center clients.

M. There shall be evidence of screening, education, and referral for postpartum mood disorders.

Additional options:

N. Exercise programs

O. Parent support groups

P. Postpartum classes

Q. Family planning

R. Well baby care

S. Circumcision

T. Nursing mother support program

U. Well woman gynecologic care

V. Public education

W. Professional education

X. Clinical investigation and/or research

3. That drugs for induction or augmentation of labor, vacuum extractors, forceps, recorded electronic fetal monitors and ultrasound imaging are not recommended during normal labor and are not appropriate for use in birth centers.

4. That a policy and procedure manual is available to practitioners and support staff at all times and that it include all aspects of birth center practice and care to childbearing families.

5. Practice protocols be provided to the consulting specialists and available to the hospital receiving transfers upon request.

VI. STAFFING & PERSONNEL

STANDARD

High-quality family-centered maternal and newborn care is provided by qualified professional and clinical staff with access to and availability of consulting clinical specialists and support by administrative and ancillary personnel consonant with the volume of clients enrolled for care and reflective of the services and program offered.

Attributes Required for Compliance with Standard:

1. Professional staff and consulting specialists provide evidence of the knowledge and skills required to provide the services offered by the center.
2. Professional staff and consulting specialists are licensed to practice their profession in the jurisdiction of the birth center.
3. Professional staff and consulting specialists provide evidence of malpractice insurance coverage and if not available inform clients that they do not carry malpractice insurance.
4. There are adequate numbers of professional and support staff on duty and on call to meet demands for services routinely provided, and in periods of high demand or emergency, to assure client safety and satisfaction; and to assure that no mother in active labor shall remain unattended.
5. There is an established, posted schedule for clinical staff and consulting specialists.
6. At each birth there shall be two staff currently certified in:
   A. Adult CPR equivalent to American Heart Association Class C basic life support
   B. Neonatal CPR equivalent to American Academy of Pediatrics/American Heart Association
7. Personnel records are maintained and secured for confidentiality on all employed, attending, and contracted staff and include but are not limited to:
   A. Qualifications
   B. Current license where indicated

C. Health examinations where required

D. Malpractice insurance carrier or explanation of why malpractice insurance is not obtainable

E. Evidence of malpractice claims

F. Annual performance evaluations and/or peer review

G. Evidence of current training and certification for CPR and infant resuscitation.

8. There are written personnel policies available to all personnel that include but are not limited to:

   A. Conditions of employment

   B. Respective obligations of employer and employee

   C. Benefits

   D. Affirmative action

   E. Grievance procedures.

9. The birth center provides for professional and non-professional staff development including but not limited to:

   A. Orientation of new staff, including emergency drills.

   B. Reference library

   C. Current journal subscriptions available

   D. In-service education programs to maintain currency in knowledge and skills used infrequently in birth center practice

   E. Participation in continuing professional education programs

   F. Involvement in activities of professional organization.

   G. Routine, periodic maternal and newborn medical emergency drills.

10. All birth center employees who are exposed to blood should have full immunization against hepatitis B or documentation of refusal.

11. Birth center personnel shall have annual training that meets OSHA regulations and any other applicable infection control guidelines.

12. Training as required by state and federal law in the area of patient safety and privacy.

VII. THE HEALTH RECORD

STANDARD

Health records of the birth center provide a format for continuity and documentation of legible, uniform, complete and accurate maternal and newborn information readily accessible to health care practitioners and maintained in a system that protects confidentiality, provides for storage, retrieval and prevention of loss.

Attributes Required for Compliance with Standard:

1. The birth center adopts a record form appropriate for use by the practitioners in the birth center containing information required for transfer to the acute care maternal and newborn hospital service.

2. The health record on each client includes, but is not limited to, written documentation of:

   A. Demographic information and client identification

   B. Orientation to program and informed consent and including a plan for payment of services

   C. Complete social, family, medical, reproductive, nutrition and behavioral history

   D. Initial physical examination, laboratory tests and evaluation of risk status

   E. Appropriate referral on ineligible clients with report of findings on initial screening

   F. Continuous periodic prenatal examination and evaluation of risk factors

   G. Instruction and education including nutritional counseling, changes in pregnancy, self-care in pregnancy, orientation to health record and understanding of findings on examinations and laboratory tests, preparation for labor, sibling preparation, preparation for early discharge, newborn assessment and care

   H. History, physical examination and risk assessment on admission to the center

   I. Monitoring of progress in labor with on-going assessment of maternal and fetal reaction to the process of labor in accordance with accepted professional standards

   J. Consultation, referral and transfer for maternal or neonatal problems including outcome of transfers.

K. Labor and birth summary

L. Physical assessment of newborn including Apgar scores, gestational age assessment, maternal newborn interaction, prophylactic procedures, and accommodation to extrauterine life and blood glucose when clinically indicated

M. Ongoing physical assessment of the mother and newborn during recovery

N. Discharge summary for mother and newborn

O. Plan for home care, follow-up, referral to support groups

P. Plan for newborn health supervision and required screening tests

Q. Late postpartum evaluation of mother, counseling for family planning and other services.

R. Screening and referral for postpartum mood disorders.

3. Reports of laboratory tests, treatments and consultations are entered promptly on health records.

4. There is a mechanism for providing the birth center with a copy of the prenatal record before labor and for sending a copy of the health record with the mother and/or newborn on referral or transfer to other levels of care.

5. Health records are protected to insure safe confidentiality and prevent loss but are available to practitioners on a 24-hour basis.

6. There is a system for periodic review of individual client records and attention to problems identified.

7. A medical record system is established with periodic review, by a qualified individual, of the center's system and policies and procedures for the maintenance, storage, retrieval and retirement of health records consistent with regulatory requirements.

8. Responsibility and accountability for the processing of health records is assigned to an individual employed by or contracted with the center.

9. Disclosure of all protected health information is made in compliance with federal and state regulations.

VIII. EVALUATION OF QUALITY OF CARE

STANDARD

There is an established program for evaluating the quality of direct care services to childbearing families, and the environment in which the services are provided, with an organizational plan to identify and resolve problems.

Attributes Required for Compliance with Standard:

1. The quality improvement program for direct maternal newborn care includes but is not limited to:
   - A. At least annual review of protocols, policies and procedures relating to the maternal and newborn care
   - B. The appropriateness of the risk criteria for determining eligibility for admission to and continuation in the birth center program of care
   - C. The appropriateness of diagnostic and screening procedures, such as laboratory studies, sonography, non-stress tests as they impact on quality of care and cost to the client
   - D. The appropriateness of medications prescribed, dispensed or administered in the birth center
   - E. The evaluation of performance of clinical practitioners practicing in the center (peer review-self evaluation).
   - F. Regular meetings of clinical practitioners to review the management of care of individual clients and make recommendations for improving the plan for care
   - G. Regular review of all transfers of mothers and neonates to hospital care to determine the appropriateness and quality of the transfer
   - H. Regular review and evaluation of all problems or complications of pregnancy, labor and postpartum and the appropriateness of the clinical judgment of the practitioner in obtaining consultation and attending to the problem
   - I. Evaluation of staff on ability to manage emergency situations by periodic drills for fire, maternal/newborn emergencies, power failures, and natural disasters, that are held regularly.

2. The quality improvement program for maintaining a safe, home-like environment includes but is not limited to:

   A. Routine testing of the efficiency and effectiveness of all equipment (e.g. sphygmomanometer, doptones, sterilizers, resuscitation equipment, transport equipment, oxygen equipment, communication equipment, heat source for newborn, smoke alarms, fire extinguishers

   B. Routine review of housekeeping procedures and infection control

   C. Evaluation of maintenance policies and procedures for heat, ventilation, emergency lighting, waste disposal, water supply and laundry and kitchen equipment

3. The quality improvement program monitors and promotes quality of care to clients and the community through an effective system for collection and analysis of data which includes but is not limited to:

   A. Utilization of the following services:
      1) orientation sessions
      2) childbirth related educational programs
      3) time in birth center before birth
      4) time in center after birth
      5) home visits postpartum
      6) follow-up office visits postpartum (mother)
      7) follow-up office visits for newborn
      8) type of anesthesia/analgesia used
      9) neonatal morbidity
      10) maternal morbidity

   B. Outcomes of care provided:
      1) women registered for care
      2) antepartum attrition rate
      3) antepartum transfer rate
      4) women admitted to center for intrapartum care
      5) births in the center
      6) births enroute to the center
      7) maternal intrapartum transfer rate
      8) maternal postpartum transfer rate
      9) newborn transfer rate
      10) type of delivery: NSVD or other
      11) episiotomies

12) third and fourth degree lacerations
13) c-section and operative vaginal delivery rates
14) infants with birth weight: less than 2500 grams or greater than 4500 grams
15) Apgar scores 6 and below at five minutes
16) neonatal mortality and morbidity
17) maternal mortality and morbidity

C. Reasons for transfers:
1) antepartum
2) intrapartum, including pre-admit transfers
3) postpartum
4) newborn

4. The quality improvement program evaluates client satisfaction with services provided, and demonstrates a plan to address issues/concerns raised by clients.

5. When appropriate, outside consultation/expertise is sought to review problems identified by the quality improvement program.

6. Action to resolve problems is initiated and includes but is not limited to:

A. Administrative or supervisory action

B. In-service education

C. Modification of policies and procedures

D. Revision of risk criteria

E. Revision of health record or other record forms.

7. The quality improvement program includes re-evaluation to determine that action taken has resolved the identified problem.

IX. RESEARCH ACTIVITIES

PREAMBLE

The term "research" could be used in reference to gathering and analyzing information on at least two levels of effort in a freestanding birth center. One level is the variety of investigations that relate to individual or multicenter studies in areas of market research, operation reporting, outcome analysis and reporting, or user evaluation of programs and services. Protocols must be established to protect the confidentiality of client information in these endeavors. Human subject protections as outlined by the U.S. Federal Office for Protection from Research Risks (OPRR) Guidelines should also be followed and documented as appropriate in either level/type of research mentioned in this document. This is especially important in that birth center research of any type usually involves subjects which are considered "vulnerable populations" (i.e. pregnant women and their infants).

This standard applies primarily to the second level of research that involves direct or hands on physical, emotional involvement of the birth center's clients when the center is involved in individual or multicenter trials of the use of:

A) Investigational drugs, devices or procedures deemed safe in the acute care setting such as, but not restricted to, medicines or procedures for altering the women's progress in labor, medicines or procedures for relief of pain or other interventions for use in the perinatal period

or

B) Alternative therapies which may seem appropriate for use in birth centers such as, but not restricted to, water birth, homeopathic or herbal medicines, or other alternative interventions/therapies for use in the perinatal period ("alternative" is defined here as primarily low-technology interventions which are not generally used in the mainstream medical/hospital setting). Alternative therapies must have some prior evidence which suggests they can be used safely in a birth center setting on pregnant or laboring women.

STANDARD

When research is conducted by the birth center or by the employees or affiliates of the birth center or when the birth center is used as a research site, such that the birth center patients and/or staff are the subjects of research, the research must be conducted by qualified researchers (defined here as having evidence in formal training and/or experience in the conduct of clinical, epidemiologic, or sociologic research) in accordance with written approved research policies and procedures by staff trained to conduct such research and in a manner that protects the client's health, safety and right to privacy, and protects the birth center and its clients from unsafe practices.

Attributes Required for Compliance with Standard:

1. Protocols for conducting research are approved by the governing body of the birth center after the review by the professional staff and by the appropriate birth center medical consultants.

2. Any research activities carried out within the organization are appropriate to the expertise of staff and the resources of the organization.

3. Rights and welfare of every research subject are adequately protected.

4. Research activity is monitored and progress periodically reported to the governing board.

5. Final results of research activity are reported to AABC, for consideration and dissemination to other birth centers, and for consideration by the AABC Standards Committee for possible incorporation in accepted birth center standards of practice.